computer assisted Web survey (CAWI); self-administered paper-and-pen (Paper/pen); or an interviewer administered computer assisted telephone interview (CATI). Proxy interviews for those cohort members unable to complete the follow up will be completed by using one of the three methods as well. Secondary objectives include evaluating biological markers that may be associated with agricultural exposures and risk of certain types of cancer. Questionnaire data will be collected by using computer assisted telephone interview (CATI) and in-person interview (CAPI) systems for telephone screeners and home visit interviews, respectively. Some respondents will also be asked to participate in the collection of biospecimens including blood, urine, and buccal cells (loose cells from the respondent's mouth). The findings will provide valuable information concerning the potential link between agricultural exposures and cancer and other chronic diseases among agricultural Health Study cohort members, and this information may be generalized to the entire agricultural community.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 10,465.

Estimated Annualized Burden Hours

TABLE A.12–1—ESTIMATES ANNUALIZED BURDEN HOURS

Type of respondent	Form	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Private and Commercial Applicators and Spouses.	Reminder, Missing, and Damaged Scripts for Buccal Cell.	100	1	5/60	8
Private Applicators	BEEA CATI Screener	480	1	20/60	160
Private Applicators	BEEA Home Visit CAPI, Blood, & Urine x 1.	160	1	30/60	80
Private Applicators	BEEA Schedule Home Visit Script	20	3	5/60	5
Private Applicators	BEEA Home Visit CAPI, Blood, & Urine x 3.	20	3	30/60	30
Private Applicators	Paper/pen, CAWI or CATI	13,855	1	25/60	5,773
Spouses	Paper/pen, CAWI or CATI	10,201	1	25/60	4,250
Proxy	Paper/pen, CAWI or CATI	635	1	15/60	159
Total					10,465

Dated: January 30, 2013.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, NCI, NIH.

[FR Doc. 2013–02503 Filed 2–4–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request: Women's Health Initiative Observational Study

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: The Women's Health Initiative (WHI) Observational Study. *Type of Information Collection Request:* Revision OMB #0925–0414. *Need and Use of Information Collection:* This study will be used by the NIH to evaluate risk factors for chronic disease among older women by developing and following a large cohort of postmenopausal women and relating subsequent disease development to baseline assessments of historical, physical, psychosocial, and physiologic characteristics. In addition, the observational study will complement the clinical trial (which has received clinical exemption) and provide additional information on the common causes of frailty, disability and death for postmenopausal women, namely, coronary heart disease, breast and colorectal cancer, and osteoporotic fractures. Continuation of follow-up for ascertainment of medical history update forms will provide essential data for outcomes assessment for this population of aging women. *Frequency of Response:* Annually. *Affected Public:* Individuals or households and health care providers. *Type of Respondents:* Study participants, next-of-kin, and physician's office staff. The annual reporting burden is as follows:

ESTIMATE OF ANNUAL HOUR BURDEN

Type of respondent	Number of respondents	Frequency of response	Average time per response	Annual hour burden
OS Participants	41,495	1	20/60	13,929
Next of kin	936	1	6/60	92
Physician/Office Staff	17	1	5/60	1.4
Totals	42,448			14,023

[1] Annual burden is placed on health care providers and respondent relatives/informants through requests for information which will help in the compilation of the number and nature of new fatal and nonfatal events.

The annualized cost to respondents is estimated at $308,218, assuming respondents time at the rate of $22 per hour and healthcare provider time at the rate of $53 per hour. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Shari Eason Ludlam, MPH, Project Officer, NIH, NHLBI, 6701 Rockledge Drive, MSC 7913, Bethesda, MD 20892–7934, or call non-toll-free number 301–402–2900 or Email your request, including your address to: *Ludlams@nhlbi.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: January 25, 2013.

Michael Lauer,

Director, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute, National Institutes of Health.

Dated: January 28, 2013.

Lynn W. Susulske,

Government Information Specialist. Freedom of Information and Privacy Act Branch, NHLBI, National Institutes of Health.

[FR Doc. 2013–02505 Filed 2–4–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request: Recipient Epidemiology and Donor Evaluation Study-III (REDS–III) Request for Generic Clearance

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below. This proposed information collection was previously published in the **Federal Register** in Volume 77, No. 199/ Monday, October 15, 2012, pages 62518–62519, and allowed 60-days for public comment. No comments have been received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Recipient Epidemiology and Donor Evaluation Study-III (REDS–III). *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The objective of the Recipient Epidemiology and Donor Evaluation Study-III (REDS–III) program is to ensure safe and effective blood banking and transfusion medicine practices through a comprehensive, multifaceted strategy involving basic, translational, and clinical research to improve the benefits of transfusion while reducing its risks. The conduct of epidemiologic, survey, and laboratory studies is the cornerstone of REDS–III and its predecessors, the REDS and REDS–II programs. Over the past 20 years, the National Heart, Lung, and Blood Institute (NHLBI) REDS programs have proven to be the premier research programs in blood collection and transfusion safety in the United States. Successive renditions of the REDS programs have built upon the many successes that this research network has realized over the years while being responsive to changing research and clinical needs, and adapting to emerging priorities. Research findings have served to improve the screening of donors and collected blood products, blood banking practices, diagnoses, and the basic science principles of transfusion medicine.

While significant progress has been made, transfusion therapy—a very commonly used therapy affecting about six million recipients annually in the U.S.—remains one of the least understood medical procedures. REDS–II conducted studies of blood donor health but much more needs to be learned, including how donor genetic or environmental factors may affect the quality of collected blood components and influence non-infectious transfusion complications in recipients. Additionally, there is always the potential that a new, emerging or re-emerging infection may pose a threat to the safety of the U.S. blood supply. Much of the success of the REDS programs was due to their ability to respond in a timely fashion to potential blood safety threats such as West Nile Virus (WNV) in 2002 or Xenotropic Murine Leukemia Virus Related Virus (XMRV) in 2009. Globally, the threat of HIV and other blood-borne infections to blood safety remains real and has to be closely monitored. Therefore, continuing collection of new scientific evidence through REDS–III is both critical to public health in the U.S. and to countries struggling with the HIV epidemic where blood safety and availability are major concerns. Additionally, the research areas encompassed in REDS–III have been and continue to be hypothesis generating, leading to the development of new basic and translational research projects with implications well beyond the fields of blood banking and transfusion medicine. REDS–III has also been charged with the tasks of education and training and integration of these components in a transfusion medicine research network.

With this submission, the REDS–III Study seeks approval from OMB to develop research studies with data collection activities using focus groups, cognitive interviews, questionnaires and/or qualitative interviews following all required informed consent procedures for respondents and parents/ caregivers as appropriate. With this generic clearance, study investigators will be able to use the OMB-approved data collection methods where appropriate to plan and implement time sensitive studies. Such studies that fall within the overall scope of this submission will be subjected to expedited review and approval by OMB before their implementation. Additionally, studies are reviewed by an NHLBI Observational Study Monitoring Board (OSMB) and by all relevant IRBs.